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# Guidance for the Reregistration of Pesticide Products Containing Cyhexatin as the Active Ingredient

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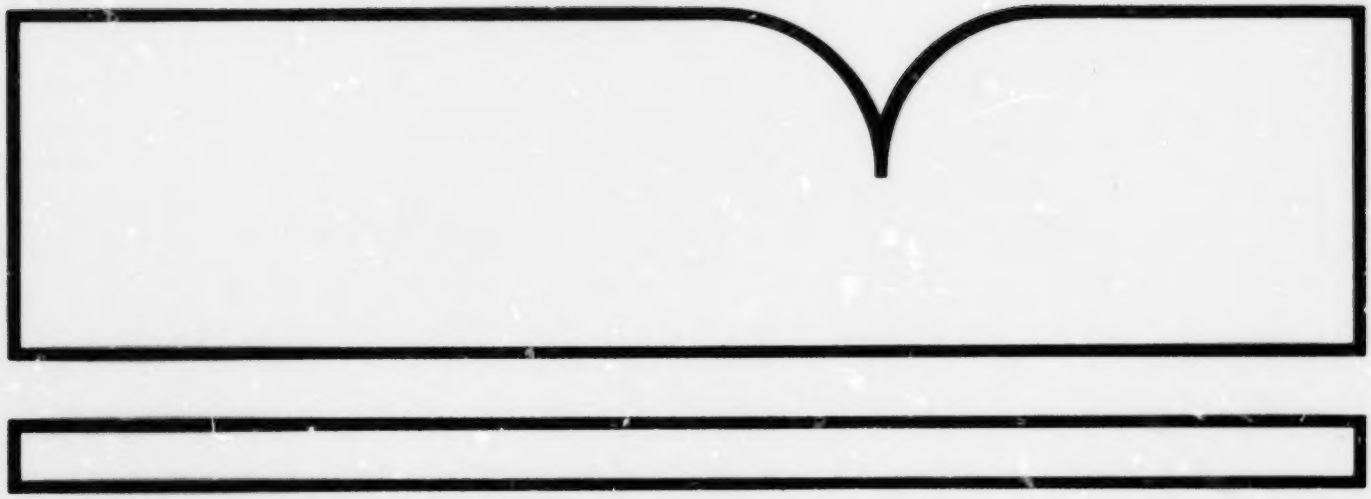

U.S. Department of Commerce
National Technical Information Service
NTIS

PB86-173184

# GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

CYHEXATIN
(101601)

CASE NUMBER 237

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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## INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we were also looking for potential hazards that may be associated with the end-use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing-use products (basic suppliers of the active ingredient). End-use producers who do not qualify for the formulator's exemption* are also required to submit these data.

* The formulator's exemption applies to a registrant if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

An end-use producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. An end-use registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If your decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

| PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM | ACTION(S) REQUIRED TO MAINTAIN REGISTRATION |
|---|---|
| I. Products That Do Not Qualify For the Formulator's Exemption | |
| A. Single Active Ingredient Products* | These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document. |
| B. Multiple Active Ingredient Products | These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required. |
| II. Products That Do Qualify For The Formulator's Exemption | Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices. |

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

## II. REGULATORY POSITION AND RATIONALE

### A. Introduction

This chapter contains the Agency's regulatory position and rationale on manufacturing-use products containing the pesticide cyhexatin as a sole active ingredient. The Agency bases its position and rationale on a consideration of all uses of cyhexatin appearing on pesticide products registered under Sections 3 and 24(c) of the FIFRA as well as on products authorized for distribution in intrastate commerce under 40 CFR 162.17. The Agency has reviewed the known chemical, environmental, and toxicological characteristics of this pesticide and its established tolerances for residues in or on food and feed commodities. From these considerations the Agency sets forth the data and labeling requirements that must be met by registrants and applicants for registration of cyhexatin manufacturing-use products (MPs) in order for their products to be registered or reregistered under this Standard. Unique labeling requirements and certain data needs for end-use products (EPs) containing cyhexatin are also established by this Standard.

Only those data and labeling requirements for current and future substantially similar MPs and EPs are addressed here. Applications to register products that differ appreciably from those described in this Standard may be subject to additional data and/or labeling requirements.

B. Description of Chemical and Use Profile

Cyhexatin is the American National Standards Institute (ANSI), International Organization For Standardization (ISO), and British Standards Institute (BSI) approved name for a miticide produced by Dow Chemical Co., U.S.A., in Germany by Bayer A.G. and in Taiwan by GENP International.

The chemical name for cyhexatin is tricyclohexylhydroxystannane. Another name is tricyclohexyltin hydroxide. Trade names include Acarstin®, Plictran® and Dowco® 213.

Other identifying characteristics and codes are:

| | |
|---|---|
| Empirical Formula: | $C_{18}H_{34}OSn$ |
| Molecular Weight: | 385 |
| CAS Registry No.: | 13121-70-5 |
| ENT Registry No.: | 27-395-X |
| Shaughnessy No.: | 101601 |

Some physical and chemical properties of the 95% technical cyhexatin product is that it is a white crystalline powder, nearly odorless, has no true melting point, degrades to bis-tricyclohexyltin oxide at 121-135°C, decomposes at 228°C and is soluble at various amounts in organic solvents such as carbon disulfide, carbon tetrachloride, chloroform, chlorobenzene, methyl chloride tetrahydrofuran, and toluene. Cyhexatin is practically insoluble in water.

vapor pressure is negligible at 25°C for the pure active ingredient of cyhexatin. Cyhexatin is stable in aqueous suspensions with neutral and alkaline pH. Cyhexatin reacts ionically in the presence of a strong acid to form salts, and cyhexatin is converted by exposure to UV radiation to dicyclohexyltin oxide, then to cyclohexylstannoic acid.

There are three products currently registered which contain cyhexatin as an active ingredient of which one is a technical cyhexatin product (95%). The other two are 50% wettable powder formulations. These are all single active ingredient formulations. There are eight intrastate products. Cyhexatin is a miticide registered for use on almonds, apples, citrus fruits, hops, macadamia nuts, nectarines, peaches, pears, plums (fresh prunes), strawberries, walnuts, ornamental plants and greenhouse grown carnations, chrysanthemums, poinsettias, and roses. Foliar applications are made when pests first appear and are repeated as needed; applications to apples, citrus fruits, and pears may be made with aerial equipment. Apples and walnuts comprise most of the use of cyhexatin in the U.S.

Tolerances for food/feed items are currently expressed in terms of combined residues of cyhexatin and its organotin metabolites (expressed as cyhexatin) (40 CFR 180.144, 21 CFR 561.400, and 21 CFR 193.430).

C. Regulatory Position and Rationale

Based on a review and evaluation of all available data and other relevant information on cyhexatin, the Agency has made the following determinations:

1. All products containing cyhexatin as a sole active ingredient may continue to be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Guidance Document. Registrants must provide or agree to develop additional data, as specified in Tables A and B in order to maintain existing registrations or to permit new registrations.

   Rationale: Under FIFRA, the Agency normally does not cancel or withhold registration simply because data are missing or are inadequate (see Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated after they are received and the Agency will determine at that time whether they will affect the registration(s) of cyhexatin.

The Agency will not allow any significant new uses* to be established for cyhexatin until the toxicological and residue chemistry data deficiencies identified in Table A have been received and evaluated and the Agency concludes that new uses are supportable.

Rationale: The Agency is unable to complete a tolerance reassessment of cyhexatin because of extensive residue chemistry and toxicology data gaps. The data requested in Table A are needed for EPA to calculate an acceptable daily intake (ADI) level of cyhexatin and its metabolites and to reassess the present tolerances. For a complete discussion of the tolerance reassessment for cyhexatin, see section G entitled "Tolerance Reassessment."

3. The Agency is requiring that existing food additive tolerances for dried prunes and dried hops be amended and that food and feed tolerances be proposed and established for wet apple pumace, citrus oil and molasses and possibly spent hops.

Rationale: Current established food additive tolerances for dried prunes (4ppm) and dried hops (90 ppm) are considered

* The terminology "significant new use" is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximal Residue Concentration of greater than 1%.

inadequate from the Agency's reassessment of the existing residue data for these commodities. These data demonstrate that residues will concentrate at higher factors. These tolerances must be amended to 7 ppm and 135 ppm, respectively, unless it can be demonstrated otherwise with additional data. Also, existing data demonstrate that cyhexatin and its metabolites concentrate such that food and feed additive tolerances must be proposed and established for wet apple pumace, citrus oil and molasses. Required data for spent hops, after it is received and evaluated, may also demonstrate the need for a tolerance on this commodity.

4. The Agency is requiring extensive environmental fate and chemistry data to characterize cyhexatin's behavior in the environment, including its potential to leach through soil.

Rationale: At present, only very limited data are available to assess the environmental fate of cyhexatin or to characterize its potential for contaminating ground water. These data suggest that cyhexatin leaches slowly. The Agency has become increasingly concerned about the presence of pesticide chemicals in ground waters in the United States and has identified a number of chemicals, including cyhexatin, which may have the potential to enter ground waters based on factors such as chemical structure, solubility and use patterns.

5. The Agency is requiring that labels be revised to require the use of protective clothing. It is also requiring that data gaps in the existing exposure and toxicology data base be filled. Upon receipt and review of the exposure and toxicology data, the Agency will determine if field reentry restrictions and additional protective clothing requirements are necessary.

Rationale: Adequate toxicology data are not available to fully characterize the acute, subchronic and chronic effects of cyhexatin in humans. Acute oral and eye irritation toxicity data are sufficient to categorize the current MP and EP formulations as Toxicity Category II. Product labeling precautions inform and instruct applicators to minimize exposure and therefore acute hazards. The existing toxicology data base does not include any studies conducted by Industrial Bio-Test Laboratories, Inc.

Between the years of 1966 and 1981, the Pesticide Incident Monitoring System (PIMS) report includes 14 humans, 1 domestic animal and no environmental incidents in which cyhexatin alone was involved. During that same time, there were 26 human, no domestic animal and 1 environment incidents reported in which cyhexatin in combination with other pesticides were involved. Most of the human incidents were agricultural related and a few were industrial. Circumstances of exposure

were mixed between the various handling and application operations (mixing, loading, application, flagging) and involved different exposures--dermal, inhalation and eye contact. Usually, the exposures were caused by the lack of or improper use of protective clothing, spray drift or spills. Contact dermatitis was a common effect from dermal exposure. Because of these reported incidents, it is necessary to prescribe protective clothing. This requirement is presented in Section F (Required Labeling).

6. Studies to determine the effects on nontarget avian and aquatic organisms are being required.

Rationale: Acute toxicity studies indicate that cyhexatin is highly toxic to birds. Due to this toxicity and the probable repeated exposure resulting from multiple applications, the avian reproduction study is now required for cyhexatin. The fish early-life stage and aquatic invertebrate life-cycle studies are reserved since the currently existing environmental fate data are not sufficient for the Agency to estimate aquatic exposure. In addition, the guideline trigger for persistence in water cannot be addressed until a valid study is available. Once the Agency has reviewed these studies, it will determine if higher tier studies such as aquatic and avian field studies should be required.

7. The Agency will impose interim labeling to protect endangered species, if the generic (cluster) analysis for endangered species has not been completed in time to impose appropriate labeling in time for the 1986 growing season. At this time, no label statements are being imposed.

Rationale: Appropriate labeling for the protection of endangered species determined to be in jeopardy is being developed in conjunction with a generic (cluster) approach, rather than under this Standard. This generic approach, which entails the analysis of the effects of all pesticides on endangered species on a crop-by-crop basis, rather than a chemical-by-chemical approach, is being developed in cooperation with Federal and State enforcement agencies, the Office of Endangered Species (OES) of the U.S. Fish & Wildlife Service and the U.S. Department of Agriculture (USDA), using the extension services, and the National Agricultural Chemical Association (NACA). Since the cluster approach does not currently address small crops, those uses will be reviewed separately by the Office of Endangered Species through Section 7 consultation. A comprehensive consultation will require EPA to provide an estimated environmental concentration (EEC) for the habitats of endangered species. EEC's are made available through computer models which require environmental fate data. As shown by the data requirement tables,

minimal environmental data are available. By agreement with the Office of Endangered Species, consultation will be delayed until these data are available.

8. The Agency is requiring that use directions for end-use products for ground application to pears, peached, plums (prunes) and nectarines be amended to reflect reductions of the maximum spray gallonage from 800 to 500 gallons per acre.

   Rationale: Current spray coverage recommendations and practices for the above orchard crops follow a spray regime of 300 to 500 gallons per acre to obtain full coverage. Higher volumes are excessive. A reduction will eliminate unnecessary and excessive spray dosages and reduce the environmental impact by reducing runoff which does not contribute to efficacy.

9. Registrants of end-use products must submit revised labeling which incorporates the label precautions found in Section F.

   Rationale: The Agency believes that label statements prescribed in this Guidance Document should minimize the acute hazards associated with the oral, dermal, inhalation and ocular routes of exposure to users of cyhexatin, and should minimize the hazards to terrestrial and aquatic organisms.

D. Criteria for Registration Under This Standard

To conform to this Guidance Document, products must contain cyhexatin as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use patterns listed in Sections E and F of this document. The application for registration or reregistration of manufacturing-use products subject to this Guidance Document must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula and Certification of Ingredients statement, revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). Registrants of end-use products who qualify for the Formulator's Exemption must submit five (5) copies of draft labeling incorporating the unique label statements identified in Section F.

E. Acceptable Ranges and Limits

Product Composition Standard

To conform to this Guidance Document, manufacturing-use products must contain cyhexatin as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum

an minimum amounts of the active and intentionally added inert ingredients which will be present in products.

Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing cyhexatin, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed. The attached index entry lists all registered uses (and intrastate label uses*) as well as approved maximum application rates and frequencies.

F. Required Labeling

All manufacturing-use and end-use cyhexatin products must bear appropriate labeling as specified in 40 CFR 162.10. In addition to the above, the following information must appear on the labeling:

1. Ingredient Statement

The ingredient statement for MPs must list the active ingredient as:

Cyhexatin (tricyclohexylhydroxystannane) ....._____%.

* Product uses that appear only on the labels of intrastate products have not been subject to review under sec. 3 of the FIFRA. Therefore, these uses may not be added to the label of any product registered under sec. 3 until the supporting data have been submitted, reviewed and found to be acceptable.

2. Use Pattern Statements

All manufacturing-use cyhexatin products must state that they are intended for formulation into other manufacturing-use products or end-use products for uses accepted by the U.S. Environmental Protection Agency. A limiting factor will be data that supports these use patterns. No use may be included on the label for which the registrant fails to agree to comply with the data requirements in either Table A or Table B for that use pattern. The attached "EPA Index to Registered Pesticides" entry summarizes all currently acceptable uses for cyhexatin including sites of application, target pests, dosage rates, restrictions and limitations, and the method and frequency of application.

3. Acute Toxicity Precautionary Statements

Labels for manufacturing-use cyhexatin products must bear statements reflecting the compound's acute human toxicity. The acute oral and eye irritation toxicity data are sufficient to categorize the current MP and EP formulations as Toxicity Category II. The required precautionary statements associated with this category are specified in 40 CFR 162.10.

4. Protective Clothing

Because of the reported incidents of dermatitis, the following protective clothing statements are required for product labels.

a. Manufacturing-Use Products:

"When handling this product wear chemically resistant gloves."

The use of goggles is also required.

b. End-Use Products:

"When mixing, loading, and applying wear chemically resistant gloves."

Use of goggles, a mask or pesticide respirator is required.

5. Environmental Hazards Statements

a. The following revised environmental hazard statement must appear on all MP labels:

"ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

b. For end-use products the environmental hazards statement shall read:

"ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not

apply directly to water or wetlands. Drift and runoff from treated areas may be hazardous to fish in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or incorporate spills."

6. EP labels must be revised to reduce the recommended spray gallonage from 300-800 gallons to 300-500 gallons per acre for ground application to pears, peaches, plums (prunes) and nectarines.

G. Tolerance Reassessment

The adequacy of the established tolerances (40 CFR 180.144, 21 CFR 193.430 and 561.400 and Table I), covering residues of cyhexatin in crop and animal products cannot be determined at the present time due to significant data gaps in residue chemistry and toxicology. The nature of residues in plants and animals and the chronic toxicity of cyhexatin has not been adequately described. Available residue data are sufficient to characterize the expected residue levels of cyhexatin in or on the following raw agricultural commodities (RACs): hops, macadamia nuts, and strawberries. Additional crop residue data are required to support the established tolerances for residues in or on peaches, plums, nectarines, apples, pears, almonds, almond hulls, walnuts, and citrus fruits. The adequacy of the tolerances for residues in dried citrus pulp and dried apple pomace cannot be determined until the

adequacy of the tolerances for residues in the RACs (apples and citrus) has been ascertained. Data are available to the Agency which indicate that residues in dried prunes concentrate by a factor of 7 over residues present in the raw agricultural commodity. The tolerances for residues in dried prunes must be revised from 1 ppm to 7 ppm to reflect this potential 7X concentration. Additional data to support the established tolerance of 30 ppm or a proposal for a tolerance revision are needed for dried hops; data available to the Agency suggest that a revision to 135 ppm may be appropriate.

In addition to the conclusions given above regarding established tolerances, the following requirements pertain to residues in processed products: (i) after the adequacy of the apple tolerance is determined, a food additive tolerance at 3x that of the tolerance for residues in or on apples must be proposed for residues in wet apple pomace; (ii) a food additive tolerance at 22x that of the tolerance for residues in or on citrus fruit must be proposed for residues in citrus oil; (iii) a food and feed additive tolerance at 2x that of the tolerance for residues in or on citrus fruit must be proposed for residues in citrus molasses; and, (iv) data are needed to determine whether residues concentrate in spent hops, a processed product of fresh hops.

The food and feed additive tolerance mentioned above are required because data available to the Agency indicate that residues in processed fruits are greater than residues in raw agricultural commodities.

The acceptable daily intake (ADI) for cyhexatin was previously based on the no observable effect level (NOEL) of 0.75 mg/kg of the 2-year dog feeding study. However, a recent review of this study indicates effects at this level which was also the lowest tested dosage level. Therefore, without a NOEL this study is now classified as supplementary and can no longer be utilized as a basis for an ADI calculation. There are no other available appropriate studies to the Agency on which the ADI for cyhexatin can be based. The Agency has concluded that the chronic toxicology is inadequate and therefore is requiring the full complement of studies: chronic feeding, oncogenicity, reproduction and teratology studies.

Cyhexatin

TABLE I

SUMMARY OF PRESENT TOLERANCES

| Commodity | Tolerances (ppm) United States[a]/ | Canada[b]/ | Mexico | International (Codex)[c]/ |
|---|---|---|---|---|
| Almonds | 0.5 | 0.3 | — | — |
| Almond Hulls | 60.0 | — | — | — |
| Apples | 2.0 | 2.0 | — | 2.0 |
| Apple pumace (dried) | 8.0 | — | — | — |
| Cattle, fat | 0.2 | — | — | — |
| Cattle, kidney | 0.5 | — | — | — |
| Cattle, liver | 0.5 | — | — | — |
| Cattle, MBYP (exec. kidney, liver) | 0.2 | — | — | — |
| Cattle, meat | 0.2 | — | — | 0.5 |
| Citrus fruits | 2.0 | 2.0 | — | 2.0 |
| Citrus pulp (dried) | 8.0 | — | — | — |
| Goat, fat | 0.2 | — | — | — |
| Goat, kidney | 0.5 | — | — | — |
| Goat, liver | 0.5 | — | — | — |
| Goats, MBYP (except kideny, liver) | 0.2 | — | — | — |
| Goat, meat | 0.2 | — | — | 0.5 |
| Hogs, fat | 0.2 | — | — | — |
| Hogs, kidney | 0.5 | — | — | — |
| Hogs, liver | 0.5 | — | — | — |
| Hogs, MBYP (exec. kidney, liver) | 0.2 | — | — | — |
| Hogs, meat | 0.2 | — | — | 0.5 |
| Hops | 30.0 | — | — | — |
| Hops (dried) | 90.0 | — | — | — |
| Horses, fat | 0.2 | — | — | — |
| Horses, kidney | 0.5 | — | — | — |
| Horses, liver | 0.5 | — | — | — |
| Horses, MBYP (exec. kidney, liver) | 0.2 | — | — | — |
| Horses, meat | 0.2 | — | — | 0.5 |
| Macadamia nuts | 0.5 | — | — | — |

Cyhexatin

TABLE I

SUMMARY OF PRESENT TOLERANCES (Con't.)

| Commodity | Tolerances (ppm) United States[a]/ | Canada[b]/ | Mexico | International (Codex)[c]/ |
|---|---|---|---|---|
| Milk, fat (= N in whole milk) | 0.05 | — | — | — |
| Nectarines | 4.0 | — | — | — |
| Peaches | 4.0 | 4.0 | — | 5.0 |
| Pears | 2.0 | 2.0 | — | 2.0 |
| Plums or Prunes (fresh) | 1.0 | 1.0 | — | 2.0 |
| Prunes (dried) | 4.0 | — | — | — |
| Sheep, fat | 0.2 | — | — | — |
| Sheep, kidney | 0.5 | — | — | — |
| Sheep, liver | 0.5 | — | — | — |
| Sheep, MBYP (exec. kidney, liver) | 0.2 | — | — | — |
| Sheep, meat | 0.2 | — | — | 0.5 |
| Strawberries | 3.0 | 2.0 | — | 2.0 |
| Walnuts | 0.5 | 0.3 | — | — |

Note, a = The U.S. tolerance is expressed in terms of residues of cyhexatin and its organotin metabolites; b = The Canadian tolerance in terms of combined residues of cyhexatin DCHTO and CHSA; c = Cocex is for cyhexatin and DCHTO.

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Guideline Citation and Name of Test | Test Substance | Guidelines Status | Are Data Required Yes | Are Data Required No | Footnote Number | Data Must Be Submitted Within Timeframes Listed Below 2/ |
|---|---|---|---|---|---|---|
| §158.120 Product Chemistry | | | | | | |
| Product Identity: | | | | | | |
| 61-2 - Product Identity and Disclosure of Ingredients | TGAI | R | [X] | [ ] | _____ | 7 Months |
| 61-3 - Discussion of Formation of Impurities | TGAI | R | [X] | [ ] | _____ | 7 Months |
| Analysis and Certification of Product Ingredients | | | | | | |
| 62-1 - Preliminary Analysis | TGAI | CR | [X] | [ ] | _____ | 12 Months |
| Physical and Chemical Characteristics | | | | | | |
| 63-2 - Color | TGAI | R | [ ] | [X] | _____ | - - |
| 63-3 - Physical State | TGAI | R | [ ] | [X] | _____ | - - |
| 63-4 - Odor | TGAI | R | [X] | [ ] | _____ | 7 Months |
| 63-5 - Melting Point | TGAI | R | [ ] | [X] | _____ | - - |
| 63-6 - Boiling Point | TGAI | R | [ ] | [X] | _____ | - - |

| Guideline Citation and Name of Test | Test Substance[1] | Guidelines Status | Are Data Required Yes | Are Data Required No | Footnote Number | Data must Be Submitted Within Timeframes Listed Below[2] |
|---|---|---|---|---|---|---|
| §158.120 Product Chemistry (Continued) | | | | | | |
| Physical and Chemical Characteristics (Continued) | | | | | | |
| 63-7 - Density, Bulk Density, or Specific Gravity | TGAI | R | [X] | [ ] | _____ | 7 Months |
| 63-8 - Solubility | TGAI or PAI | R | [ ] | [X] | _____ | - - |
| 63-9 - Vapor Pressure | PAI | R | [ ] | [X] | _____ | - - |
| 63-10 - Dissociation constant | PAI | R | [X] | [ ] | _____ | 7 Months |
| 63-11 - Octanol/water partition coefficient | PAI | R | [X] | [ ] | _____ | 7 Months |
| 63-12 - pH | TGAI | R | [X] | [ ] | _____ | 7 Months |
| 63-13 - Stability | TGAI | R | [X] | [ ] | _____ | 7 Months |
| Other Requirements: | | | | | | |
| 64- 1 - Submittal of samples | TGAI, PAI | CR | [ ] | [X] | _____ | - - |

1/ TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required.

2/ Data must be submitted within the indicated timeframes which begin on the date of the Registration Standard (see front cover).

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirements | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? | Timeframes For Data Submission 2/ |
|---|---|---|---|---|---|
| §158.125 Residue Chemistry | | | | | |
| 171-4 - Nature of Residue (Metabolism) | | | | | |
| - Plants | PAIRA | Partially | 00034893, 00080462, 00081491, 00112208, 00112217, 00040803, 00071437, 00112230, 00065985, 00108766, 00112232, 00065986 00112181, 00112236, 00065987, 00112207, 00112237, 00065991, 00112218, 00065993, 00112220, 00112225 | Yes[3] | 24 Months |
| - Livestock | PAIRA and Plant Metabolites | Partially | 00112187, 00112217 | Yes[4] | 18 Months |
| 171-4 - Residue Analytical Method | | | | | |
| - Plant residues | TGAI and Metabolites | Yes | 00040803, 00071437, 00112236, 00065985, 00108766, 00112237, 00065986, 00112218, 00065987, 00112225, 00065991, 00065993, 00112232 | Reserved | |
| - Animal residues | TGAI and Metabolites | Yes | 00112207, 00112218, 00112220, 00112230 | Reserved | |
| 171-4 - Storage Stability Data | PAI | Partially | 00108766, 00112225 | Yes[6] | 13 Months |
| 171-4 - Magnitude of the Residue-Residue Studies for Each Food Use | | | | | |
| Citrus Fruits Group | TEP | Partially | 00112236 | Yes[7] | 24 Months |

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirements | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? | Timeframes For Data Submission 2/ |
|---|---|---|---|---|---|
| §158.125 Residue Chemistry (continued) | | | | | |
| 171-4 - Magnitude of the Residue - Residue Studies | | | | | |
| Pome Fruits Group | TEP | No | — | Yes[8] | 24 Months |
| Apples | TEP | Partially | 00052033, 00065984, 00065985, 00065986, 00065987, 00112181, 00112218, 00112236 | Yes[9] | 24 Months |
| Pears | TEP | Partially | 00052033, 00065986, 00065987, 00112181, 00112236 | Yes[10] | 24 Months |
| Stone Fruits Group | TEP | No | — | Yes[11] | 24 Months |
| Nectarines | TEP | Partially | 00040803 | Yes[12] | 24 Months |
| Peaches | TEP | Partially | 00040803 | Yes[13] | 24 Months |
| Plums | TEP | Partially | 00040803, 00112237 | Yes[14] | 24 Months |
| Small Fruits and Berries Group | TEP | No | — | Yes[15] | 24 Months |
| Strawberries | TEP | Yes | 00040803 | No | |
| Tree Nuts Group | TEP | No | — | Yes[16] | 24 Months |
| Almonds | TEP | Partially | 00040803, 00112237 | Yes[17] | 24 Months |
| Macadamia Nuts | TEP | Yes | 00112225 | No | |

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirements | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B) | Timeframes For Data Submission 2/ |
|---|---|---|---|---|---|
| §158.125 Residue Chemistry (continued) | | | | | |
| Walnuts | TEP | Yes | 00040803, 00112237 | Yes[18] | 24 Months |
| Misc. Commodities | - | - | — | No | |
| Hops | TEP | Partially | 00108766 | Yes[19] | 24 Months |
| Meat/milk/poultry/eggs | TEP | Partially | 00112207, 00112230, 00112232 | Reserved[20] | 18 Months |

1/ Composition: TGAI = Technical grade of the active ingredient; EP = End-use product.

2/ Data must be submitted within the indicated timeframes which begin on the date of the Registration Standard (see front cover).

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

§158.125 Residue chemistry (continued)

3/ Data reflecting the distribution and metabolism of ring-labeled [$^{119}$Sn]cyhexatin in a tree fruit (preferably apples) following foliar application at 3 lb ai/A are required.

4/ Metabolism studies utilizing ruminants are needed. Animals must be dosed for 3 days with ring-labeled [$^{119}$Sn]cyhexatin at a level sufficient to make residue identification possible. Milk must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, liver, kidney, muscle, and fat. Metabolism studies utilizing poultry are required. Hens must be dosed with ring-labeled [$^{119}$Sn] cyhexatin for 3 days at a level sufficient to permit residue identification. Eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose and residues characterized in eggs, muscle, liver, kidney, and fat.

5/ Should the data which were requested in the section entitled "Nature of the Residue in Plants" and "Nature of the Residue in Animals" indicate additional metabolites of toxicological concern or that the methods will not adequately determine all residues of concern, then submission of additional validated methods for data collection and tolerance enforcement will be required. The [$^{119}$Sn]cyhexatin labeled samples should be analyzed by both radiocounting techniques and "cold" enforcement methodology to determine the percent of the total residue measured by the enforcement method.

6/ The available storage stability data are acceptable for plant commodities; however, no data pertaining to the stability of cyhexatin residues in animal tissues or products were presented, thus, constituting a data gap.

7/ Data are needed depicting residues of cyhexatin in or on oranges, grapefruit, and lemons harvested the same day as the last of six foliar treatments at 10- to 14-day intervals with the 50% WP at 0.1875 lb ai/100 gal using a spray volume to runoff. Tests must be conducted in FL and CA. Alternatively, must clarify the total spray volume utilized for data submitted under PP#3F1312 (117973). A food additive tolerance for citrus oil and citrus molasses at respective levels of 22x and 2x the residues found in or on whole citrus must be proposed. An appropriate feed additive tolerance for citrus molasses at 2x the residues found in or on whole citrus must be proposed and, if necessary, a revision of the existing 8 ppm feed additive tolerance for residues in dried citrus pulp is required.

8/ To establish a pome fruits group tolerance additional data must be submitted for apples and pears. See footnotes 9 and 10 below.

9/ Information must be provided as to the gal/A/application applied in the high-volume ground application data submitted; alternatively, data must be submitted which reflect residues in or on apples harvested 14 days after the last of four applications at 1.5 lb ai/800 gal/A. Tests must be conducted in all the major U.S. apple production regions. A food additive tolerance must be proposed for residues in wet apple pomace at 3x that of the accepted tolerance for residues in or on the raw agricultural commodity (apples).

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

§158.125 Residue chemistry (continued)

10/ The available data provide insufficient support for the established tolerance for the following reasons: (i) gal/A rates were not provided for high-volume ground applications; (ii) the aerial data do not reflect use of a registered formulation; and (iii) no low-volume ground application data were provided. In our opinion, the available ULV aerial data for apples may be used to support low-volume ground and aerial use on pears. Also, since data have been requested reflecting high-volume ground applications to apples, no additional data reflecting such use on pears are needed. It should be noted, however, that translated data may not be used to support a crop group tolerance.

11/ To establish a stone fruits group tolerance additional data must be submitted for peaches and plums (prunes) (see footnotes 13 and 14 below) and for one additional crop member of this group. Data for cherries are currently under review.

12/ Available data are insufficient for the evaluation of the adequacy of the established tolerance for the combined residues for cyhexatin and its organotin metabolites in or on nectarines since no data were submitted reflecting aerial or ULV ground application. No additional data reflecting aerial application will be required since the aerial application data requested for peaches may be translated to nectarines. However, the following additional data are required:

- Data from tests (in CA) reflecting low volume (40 gal/A) ground application of the 50% WP at 1.25 lb ai/A at a seasonal maximum of 3 lb ai/A; samples must be harvested on the day of the last application.

13/ Residue data for peaches in CA and SC receiving aerial treatment of the 50% WP at 1.25 lb ai/A in 15 gal water, reflecting a seasonal use rate of 3 lb ai/A, and a 1-day PHI are required. Residue data for peaches are required. Samples must be collected on the day of the last treatment. Also, additional data from tests in CA reflecting ULV ground and aerial application of 1.25 lb ai/A in at least 15 gal water/A, and a seasonal use rate of 3.0 lb ai/A, must be submitted.

14/ Residue data from tests in CA, using ground equipment to apply the 50% WP at 4.5 lb ai/A per season, at 0.1875 lb ai/100 gal of water (dilute spray), and, in separate tests, at 1.25 lb ai/A (40 gal/A) are required. Samples must be collected immediately after the last treatment. Residue data from CA tests reflecting aerial application of the 50% WP at 1.25/15 gal/A (using 3 lb ai/A per season), and a 1-day PHI are required. An appropriate tolerance revision must be proposed for residues in or on dried prunes.

15/ To establish a small fruits and berries group tolerance residue data are required for three additional crop members of this group (blackberry or other Rubus spp., blueberry and cranberry).

16/ To establish a tree nuts group tolerance additional data are needed for almonds and walnuts (see footnotes 17 and 18 below) and for an additional representative nut crop (pecans).

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

§158.125 Residue Chemistry (continued)

17/ Residue levels on or in almonds and almond hulls from trees receiving at least three applications of 1.25 lb ai/A of the 50% WP (for a seasonal total of at least 4.5 lb ai/A) by ground ULV application, with a 0-day PHI are required. These tests must be conducted in CA. Additional data on residues on/in almond hulls and nuts are required. These data must be from CA tests reflecting a 1.25 lb ai/A use rate, a seasonal use rate of 4.5 lb ai/A, ULV application by ground equipment, and no PHI.

18/ The available data are inadequate for the determination of the adequacy of the established tolerance for residues of cyhexatin and its organotin metabolites in or on walnuts, since only one test reflecting ULV application was submitted (and it did not reflect a 0-day PHI). The required data for ULV ground application for almonds can be translated to walnuts. These translated data cannot be used to support a crop group tolerance.

19/ Data reflecting residues in dried hops processed from fresh hops bearing measurable weathered residues are required. Alternatively, the tolerance for residues in dried hops may be revised. If so, we recommend a level of 135 ppm (4.5 x 30). Data reflecting residues in spent hops processed from fresh hops bearing measurable weathered residues are required. If residues are found to concentrate in spent hops, an appropriate feed additive tolerance must be proposed.

20/ The nature of residues in ruminants (including milk) and poultry (including eggs) is not adequately understood. The adequacy of the established tolerances and of the data submitted in support of the established tolerances cannot be assessed at the present time. Upon receipt of the data required under the section "Nature of Residue in Animals," the adequacy of the available data and the established tolerances will be assessed.

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § (c)(2)(B)? Timeframe for Data Submission 3/ | |
|---|---|---|---|---|---|---|
| §158.130 Environmental Fate | | | | | | |
| DEGRADATION STUDIES-LAB: | | | | | | |
| 161-1 - Hydrolysis | TGAI or PAIRA | A,B,F | No | - | Yes | 9 Months |
| Photodegradation | | | | | | |
| 161-2 - In water | TGAI or PAIRA | A,B | No | - | Yes | 9 Months |
| 161-3 - On soil | TGAI or PAIRA | A | No | - | Yes | 9 Months |
| 161-4 - In air | TGAI or PAIRA | A | No | - | Reserved[4] | - |
| METABOLISM STUDIES-LAB: | | | | | | |
| 162-1 - Aerobic Soil | TGAI or PAIRA | A,B,F | No | - | Yes | 27 Months |
| 162-2 - Anaerobic Soil | TGAI or PAIRA | A | No | - | Yes | 27 Months |
| MOBILITY STUDIES: | | | | | | |
| 163-1 - Leaching and Adsorption/Desorption | TGAI or PAIRA | A,B,F | No | 00034894 00034895 | Yes | 12 Months |
| 163-2 - Volatility (Lab) | TEP | A,F | N/A[4] | 00081485, 00081487 00034894 | No | - |
| 163-3 - Volatility (Field) | TEP | A,F | N/A[4] | - | No | - |

TABLE A
GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.130 Environmental Fate (continued) | | | | | |
| DISSIPATION STUDIES-FIELD: | | | | | |
| 164-1 - Soil | TEP | A,B | No | - | Yes 27 Months |
| 164-4 - Combination and Tank Mixes | - | - | N/A | - | No[5] -- |
| 164-5 - Soil, Long-term | TEP | A | No | - | Reserved[6] -- |
| ACCUMULATION STUDIES: | | | | | |
| 165-1 - Rotational Crops (Confined) | PAIRA | A | No | - | Yes 39 Months |
| 165-2 - Rotational Crops (Field) | TEP | A | No | - | Reserved[7] -- |
| 165-4 - In Fish | TGAI or PAIRA | A,B | No | - | Yes 12 Months |

TABLE 7

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

§158.130 Environmental Fate (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframes which begin on the date of the Registration Standard (see front cover).
4/ No data are required because cyhexatin has negligible vapor pressure.
5/ This Guidance Document deals only with single active ingredients.
6/ No data are required pending the results of metabolism and field dissipation studies.
7/ Data may be required, depending upon the results of the confined studies.

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/ | |
|---|---|---|---|---|---|---|
| §158.140 Reentry Protection | | | | | | |
| 132-1 - Foliar Dissipation | TEP | A,B | No | - | Reserved3 | -- |
| 132-2 - Soil Dissipation | TEP | A,B | No | - | Reserved3 | -- |
| 132-3 - Dermal Exposure | TEP | A,B | No | - | Reserved3 | -- |
| 132-4 - Inhalation Exposure | TEP | A,B | No | - | Reserved3 | -- |

1/ Composition: TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data to support the establishment of reentry standards are reserved. No reentry intervals are needed for cyhexatin based on available environmental fate and toxicological data. However, if results of new required toxicity studies indicate potential problems, then studies will be required.

TABLE A
GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA 3(c)(2)(B)? | Timeframe for Data Submission 3/ |
|---|---|---|---|---|---|---|
| §158.135 Toxicology | | | | | | |
| ACUTE TESTING: | | | | | | |
| 81-1 - Oral Rat | TGAI | A,B,F | Yes | 00080464 | No | — |
| 81-2 - Acute Dermal | TGAI | A,B,F | No | - | Yes | 9 Months |
| 81-3 - Acute Inhalation - Rat | TGAI | A,B,F | Yes | 00112180 | No | — |
| 81-7 - Acute Delayed Neurotoxicity - Hen | TGAI | A,B,F | N/A[4] | - | No | |
| SUBCHRONIC TESTING: | | | | | | |
| 82-1 - 90-Day Feeding - Rodent, Non-rodent | TGAI | A,B,F | N/A[5] | - | No | |
| 82-2 - 21-Day Dermal | TGAI | A,B,F | No | - | Yes | 12 Months |
| 82-3 - 90-Day Dermal | TGAI | A,B,F | N/A[5] | - | No | — |
| 82-4 - 90-Day Inhalation - Rat | TGAI | A,B,F | N/A[5] | - | No | — |
| 82-5 - 90-Day Neurotoxicity - Hen/Mammal | TGAI | A,B,F | N/A[4] | - | NO | — |

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? | Timeframe for Data Submission 3/ |
|---|---|---|---|---|---|---|
| §158.135 Toxicology (continued) | | | | | | |
| CHRONIC TESTING: | | | | | | |
| 83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent | TGAI | A,B,F | No | - | Yes | 50 Months |
| 83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred | TGAI | A,B,F | No | - | Yes | 50 Months |
| 83-3 - Teratogenicity - 2 species | TGAI | A,B,F | No | - | Yes | 15 Months |
| 83-4 - Reproduction, 2-generation | TGAI | A,B,F | No | - | Yes | 39 Months |
| MUTAGENICITY TESTING: | | | | | | |
| 84-2 - Gene Mutation | TGAI | A,B,F | No | - | Yes | 9 Months |
| 84-2 - Chromosomal Aberration | TGAI | A,B,F | No | - | Yes | 12 Months |
| 84-4 - Other Mechanisms of Mutagenicity | TGAI | A,B,F | No | - | Yes | 12 Months |

TABLE A
GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § (c)(2)(B)? Timeframe for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.135 Toxicology (continued) | | | | | |
| SPECIAL TESTING | | | | | |
| 85-1 - General Metabolism | PAI or PAIRA | A,B,F | Yes | 00112206 | No |

1/ Composition: TGAI = Technical grade of the active ingredient.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop, B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within the indicated timeframes which begin on the date of the Registration Standard (see front cover).
4/ Cyhexatin is neither an organophosphate, nor an analog of the neurotoxic compound, hence, no delayed neurotoxicity study is required.
5/ Not applicable.

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/ | |
|---|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms | | | | | | |
| AVIAN AND MAMMALIAN TESTING: | | | | | | |
| 71-1 - Avian Oral $LD_{50}$ | TGAI | A,B,F | Partially | 00112178 | Yes[4] | 9 Months |
| 71-2 - Avian Dietary $LC_{50}$ | | | | | | |
| a. Water fowl | TGAI | A,B | No | | | |
| b. Upland game | TGAI | A,B,F | Partially | 00112178 | Yes[4] | 9 Months |
| 71-3 - Wild Mammal Toxicity | TGAI | A | N/A | - | - | |
| 71-4 - Avian Reproduction | TGAI | A,B | No | | Yes[5] | 24 Months |
| 71-5 - Simulated and Actual Field Testing- Mammals and Birds | TEP | A,B | No | | Reserved[6] | |
| AQUATIC ORGANISM TESTING: | | | | | | |
| 72-1 - Freshwater Fish $LC_{50}$ | | | | | | |
| a. Warmwater | TGAI | A,B,F | Yes | 00003503* GS00237001* | No | |
| b. Coldwater | TGAI | A,B | Yes | 00081739* | No | |
| | TEP | A | Yes | GS00237002* 00081743** | Reserved[7] | |
| 72-2 - Acute $LC_{50}$ Freshwater Invertebrate | TGAI | A,B,F | Yes | 00003503 | No | |
| 72-3 - Acute $LC_{50}$ Freshwater and Marine Organisms | TGAI | | | | | |
| a. Shrimp | | A | No | None | Yes[8] | 12 Months |
| b. Marine fish | | A | No | None | Yes[8] | " |
| c. Oyster | | A | No | None | Yes[8] | " |

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms (continued) | | | | | |
| 72-4 - Fish Early Life-Stage and Aquatic Invertebrate Life-Cycle | TGAI | A,B | No | - | Reserved 9/ |
| 75-5 - Fish Life-Cycle | TGAI | A,B | No | - | Reserved 10/ |
| 72-6 - Aquatic Organism Accumulation | TGAI, PAI OR Degradation Product | A,B | N/A | - | - |
| 72-7 - Simulated or Actual Field Testing-Aquatic Organisms | TEP | A,B | No | - | Reserved 10/ |

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food Crop; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin on the date of the Registration Standard (see front cover).

4/ The acute $LC_{50}$ is only supplemental because the birds were below the minimum age of 10 days. The acute oral $LD_{50}$ is supplemental because the birds were below the minimum age of 16 weeks.

5/ Avian reproduction study is required since repeat applications are allowed.

6/ Preliminary toxicity data indicate cyhexatin is "highly toxic" to birds. However, the lack of certain environmental fate and ecological effects studies prevent a requirement at this time for field testing. Upon Agency receipt and review of those studies, this field testing study may be required.

§158.145 Wildlife and Aquatic Organisms (continued)

7/ Pending environmental fate studies needed to develop an estimated environmental concentration.
8/ Acute estuarine and marine studies are required for crops which are grown in excess of 300,000 acres in coastal counties. Of the currently registered uses, cotton and citrus meet this requirement.
9/ Fish early life-stage and aquatic invertebrate life-cycle studies are reserved since the environmental fate data are not sufficient for computer modeling. In addition, the guideline trigger for persistence in water cannot be addressed until a valid study is available.
10/ The requirement for fish life-cycle and simulated or actual field testing, and for aquatic organisms is reserved, pending the requirement and results of the fish early life-stage and aquatic invertebrate life-cycle studies.

* Study on its own fulfills the requirement.
** Study does not on its own fulfill the requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/ | |
|---|---|---|---|---|---|---|
| §158.150 Plant Protection | | | | | | |
| 121-1 - TARGET AREA PHYTOTOXICITY | EP | B | No | - | No[3] | — |
| NONTARGET AREA PHYTOTOXICITY: | | | | | | |
| TIER I | | | | | | |
| 122-1 - Seed Germination/ Seedling Emergence | TGAI | B | No | - | No[3] | — |
| 122-1 - Vegetative Vigor | TGAI | B | No | - | No[3] | — |
| 122-2 - Aquatic Plant Growth | TGAI | B | No | - | No[3] | — |
| TIER II | | | | | | |
| 123-1 - Seed Germination/ Seedling Emergence | TGAI | B | No | - | No[3] | — |
| 123-1 - Vegetative Vigor | TGAI | B | No | - | No[3] | — |
| 123-2 - Aquatic Plant Growth | TGAI | B | No | - | No[3] | — |
| TIER III | | | | | | |
| 124-1 - Terrestrial Field | TEP | B | No | - | No[3] | — |
| 124-2 - Aquatic Field | TEP | B | No | - | No[3] | — |

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food Crop; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ These data are not required because it is believed there is no phytotoxicity problem with cyhexatin.

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.155 Nontarget Insect | | | | | |
| NONTARGET INSECT TESTING - POLLINATORS: | | | | | |
| 141-1 - Honeybee acute contact $LD_{50}$ | TGAI | A,B | Yes | 00018842 | No |
| 141-2 - Honeybee - toxicity of residues on foliage | TEP | A,B | No | - | No 3/ |
| 141-4 - Honeybee subacute feeding study | - | - | No | - | Reserved 4/ |
| 141-5 - Field testing for pollinators | TEP | A,B | No | - | No 3/ |

TABLE A

GENERIC DATA REQUIREMENTS FOR CYHEXATIN

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.155 Nontarget Insect (continued) | | | | | |
| NONTARGET INSECT TESTING - AQUATIC INSECTS: | | | | | |
| 142-1 - Acute toxicity to aquatic insects | (Reserved) | - | - | - | Reserved 5/ |
| 142-2 - Aquatic insect life-cycle study | (Reserved) | - | - | - | Reserved 5/ |
| 142-3 - Simulated or actual field testing for aquatic insects | (Reserved) | - | - | - | Reserved 5/ |
| 143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru 143-3 | (Reserved) | - | - | - | Reserved 5/ |

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aqautic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ As the data from the acute contact study indicate low toxicity, no further testing is required.
4/ Reserved pending development of test methodology.
5/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CYHEXATIN
Tricyclohexylhydroxystannane- 464-451

| Guideline Citation and Name of Test | Test Substance[1] | Guidelines Status | Are Data Required Yes | Are Data Required No | Data Must Be Submitted Within Timeframes Listed Below[2] |
|---|---|---|---|---|---|
| §158.120 Product Chemistry | | | | | |
| Product Identity: | | | | | |
| 61-1 - Product Identity and Disclosure of Ingredients | MP | R | [X] | [ ] | 6 Months |
| 61-2 - Description of Beginning Materials and Manufacturing Process | MP | R | [X] | [ ] | 6 Months |
| 61-3 - Discussion of Formation of Impurities | MP | R | [X] | [ ] | 6 Months |
| Analysis and Certification of Product Ingredients | | | | | |
| 62-1 - Preliminary Analysis | MP | CR | [X] | [ ] | 12 Months |
| 62-2 - Certification of Limits | MP | R | [X] | [ ] | 12 Months |
| 62-3 - Analytical Methods to Verify Certified Limit | MP | R | [X] | [ ] | 12 Months |
| Physical and Chemical Characteristics | | | | | |
| 63-2 - Color | MP | R | [X] | [ ] | 6 Months |
| 63-3 - Physical State | MP | R | [X] | [ ] | 6 Months |
| 63-4 - Odor | MP | R | [X] | [ ] | 6 Months |

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CYHEXATIN
Tricyclohexylhydroxystannane- 464-451

| Guideline Citation and Name of Test | Test Substance[1] | Guidelines Status | Are Data Required Yes | Are Data Required No | Data Must Be Submitted Within Timeframes Listed Below[2] |
|---|---|---|---|---|---|
| §158.120 Product Chemistry (continued) | | | | | |
| Physical and Chemical Characteristics (Continued) | | | | | |
| 63-7 - Density, Bulk Density, or Specific Gravity | MP | R | [X] | [ ] | 6 Months |
| 63-12 - pH | MP | CR | [X] | [ ] | 6 Months |
| 63-14 - Oxidizing or Reducing Action | MP | CR | [X] | [ ] | 6 Months |
| 63-15 - Flammability | MP | CR | [X] | [ ] | 6 Months |
| 63-16 - Explodability | MP | R | [X] | [ ] | 6 Months |
| 63-17 - Storage Stability | MP | R | [X] | [ ] | 15 Months |
| 63-18 - Viscosity | MP | CR | [X] | [ ] | 6 Months |
| 63-19 - Miscibility | MP | CR | [X] | [ ] | 6 Months |
| 63-20 - Corrosion Characteristics | MP | R | [X] | [ ] | 15 Months |
| Other Requirements: | | | | | |
| 64- 1 - Submittal of samples | MP | CR | [ ] | [X] | |

1/ MP = Manufacturing-use Product; R = Required; CR = Conditionally Required.
2/ Data must be submitted within the indicated timeframes which begin on the date of the Registration Standard (see front cover).

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CYHEXATIN
Tricyclohexylhydroxystannane- 464-451

| Data Requirement | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? | Timeframe for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.135 Toxicology | | | | | |
| ACUTE TESTING: | | | | | |
| 81-1 - Acute Oral - Rat | MP | Yes | 00080464 | No | |
| 81-2 - Acute Dermal | MP | No | - | Yes | 9 Months |
| 81-3 - Acute Inhalation - Rat | MP | Yes | 00112180 | No | |
| 81-4 - Primary Eye Irritation - Rabbit | MP | Yes | 00112183 | No | |
| 81-5 - Primary Dermal Irritation | MP | Yes | 00112215 | No | |
| 81-6 - Dermal Sensitization | MP | Yes | 00081748 | No | |

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted within the indicated timeframes which begin on the date of the Registration Standard (see front cover).

101601

# CYHEXATIN*

TYPE PESTICIDE: Acaricide

FORMULATIONS:
Tech (95%)
WP (50%)

GENERAL WARNINGS AND LIMITATIONS: Apply when pests first appear and repeat as needed to prevent buildup of damaging populations. If all life stages of mites are present at the time of application, a repeat application should be considered in 10 to 14 days. Thorough coverage of foliage and fruit is essential for adequate control.

Agricultural Crop Tolerances:
Macadamia Nuts - 0.5 ppm

Livestock Tolerances:
Cattle (fat, meat, meat byproducts excluding kidney and liver) - 0.2 ppm
Cattle (kidney and liver) - 0.5 ppm
Goats (fat, meat, meat byproducts excluding kidney and liver) - 0.2 ppm
Goats (kidney and liver) - 0.5 ppm
Hogs (fat, meat, meat byproducts including kidney and liver) - 0.2 ppm
Hogs (kidney and liver) - 0.5 ppm
Horses (fat, meat, meat byproducts including kidney and liver) - 0.2 ppm
Horses (kidney and liver) - 0.5 ppm
Milk (fat) - 0.05 ppm
Sheep (fat, meat, meat byproducts excluding kidney and liver) - 0.2 ppm
Sheep (kidney and liver) - 0.5 ppm

| Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations |
|---|---|---|

TERRESTRIAL FOOD CROP

General Warnings and Limitations: Do not tank mix with petroleum distillate (dormant or summer oils) or apply in the same growing season as varying degrees of foliar and fruit injury will occur to almond, nectarine, peach, plum, strawberry, and walnut.

*Plictran
tricyclohexylhydroxystannane
tricyclohexyltin hydroxide

CYHEXATIN

| | Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations |
|---|---|---|---|
| 03001AA<br>03009AA | Almond<br>Walnut | | 0.5 ppm (almonds, walnuts)<br>60 ppm (almond hulls)<br>No preharvest interval through 1.5 pounds per acre for foliar application.<br>Do not apply more than 3 pounds per acre during the growing season.<br>Do not feed or allow livestock to graze on cover crops growing in treated areas. |
| LAVASA<br>LAVBAA<br>LAVBEA | European red mite<br>Pacific spider mite<br>Twospotted spider mite | 0.125-0.1875 lb/100 gal [300-800 gal/A] or 0.5-1.25 lb/A (50% WP) | Foliar application. |
| 04001AA | Apple | | 2 ppm (apple)<br>8 ppm (dried apple pomace)<br>14 day preharvest interval through 1.5 pounds per acre for foliar application.<br>Do not make more than 3 applications or apply more than 3 pounds per acre during the growing season by aircraft.<br>Do not apply more than 6 pounds per acre during the growing season by ground equipment.<br>Do not feed or allow livestock to graze on cover crops growing in treated areas. |
| LAJAKA<br>LAVASA<br>LAVAYA<br>LAVBAA<br>LAVBBA<br>LAVBEA<br>LAVAEA | Apple rust mite<br>European red mite<br>McDaniel spider mite<br>Pacific spider mite<br>Schoene spider mite<br>Twospotted spider mite<br>Yellow spider mite | 0.125-0.1875 lb/100 gal [300-800 gal/A] or 0.5-1 lb/A or 0.5-1.5 lb/A (50% WP) | Foliar application. Apply when mites are active, at or soon after petal fall. Apply lower per acre rate by aircraft in a minimum of 5 gallons of water or higher per acre rate by low volume ground equipment. |

CYHEXATIN

| | Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations |
|---|---|---|---|
| 02000AA | Citrus Fruits (including grapefruit, lemon, lime, orange, and tangerine) | | 2 ppm (citrus)<br>8 ppm (dried citrus pulp)<br>No preharvest interval through 3 pounds per acre for foliar application.<br>Do not feed or allow livestock to graze on cover crops growing in treated areas.<br>Do not apply petroleum distillate (dormant or summer oils) within 28 days before or after application of cyhexatin in FL or within 56 days in other areas. Time applications to avoid feather growth and new growth flushes that have not hardened off since a pimpling type of injury will occur to new foliage.<br>In AZ and CA, do not apply to bearing trees during the period between the appearance of first blooms and until the fruit has hardened off, normally about mid-August, because of possible injury to the fruit.<br>Do not apply to lemon when yellow fruit is present. |
| LAVARA<br>LAJBCA<br>LAVBAA<br>LAVAKA | Citrus red mite<br>Citrus rust mite<br>Pacific spider mite<br>Texas citrus mite | 0.125-0.1875 lb/100 gal [800-1600 gal/A]<br>or<br>1-2 lb/A (50% WP) | Foliar application. Per acre rate may be applied by aircraft in a minimum of 10 gallons of water or by low volume ground equipment. |

CYHEXATIN

| | Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations |
|---|---|---|---|
| 0[illegible]AA | Hops | | 30 ppm (hops)<br>90 ppm (dried hops)<br>21 day preharvest interval through 1.97 pounds per acre for foliar application.<br>Do not apply more than 4.5 pounds per acre during the growing season.<br>Do not feed hop cones or refuse to livestock. |
| LAVBEA | Twospotted spider mite | 0.5-0.875 lb/100 gal [150-225 gal/A] or 1.1 lb/150 gal/A or 1.75 lb/ 225 gal/A (50% WP) | Foliar application. For concentrate applications, use first per acre rate for first application and second per acre rate for second and third applications. |
| 05003AA<br>05[illegible]<br>05[illegible] | Nectarine<br>Peach | | 4 ppm<br>No preharvest interval through 1.5 pounds per acre for foliar application.<br>Do not apply more than 3 pounds per acre during the growing season.<br>Do not feed or allow livestock to graze on cover crops growing in treated areas. |
| LAVASA<br>LAVAYA<br><br>LAVBAA<br>LAJAIA<br>LAVBEA | European red mite<br>McDaniel spider mite<br><br>Pacific spider mite<br>Peach silver mite<br>Twospotted spider mite | 0.125-0.1875 lb/100 gal [300-800 gal/A] or 0.5-1.25 lb/A (50% WP) | Foliar application. |

CYHEXATIN

| | Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations |
|---|---|---|---|
| 04003AA | Pear | | 2 ppm<br>14 day preharvest interval through 1.5 pounds per acre for foliar application.<br>Do not make more than 3 applications or apply more than 3 pounds per acre during the growing season by aircraft.<br>Do not apply more than 5 pounds per acre during the growing season by ground equipment.<br>Do not apply cyhexatin and petroleum distillate (dormant or summer oils) as a tank mix or separately within 28 days of each other because of possible injury to the fruit.<br>Do not feed or allow livestock to graze on cover crops growing in treated areas. |
| LAJAKA<br>LAVASA<br>L[illegible]A<br>L[illegible]A<br>LAJA0A<br>LAVBBA<br>LAVBEA<br>LAVAEA | Apple rust mite<br>European red mite<br>McDaniel spider mite<br>Pacific spider mite<br>Pear rust mite<br>Schoene spider mite<br>Twospotted spider mite<br>Yellow spider mite | 0.125-0.1875 lb/100 gal [300-800 gal/A] or 0.5-1 lb/A or 0.5-1.25 lb/A (50% WP) | Foliar application. Apply when mites are active, at or soon after petal fall. Apply lower per acre rate by aircraft in a minimum of 5 gallons of water or higher per acre rate by low volume ground equipment. |
| 05006AA | Plum (Prune) | | 1 ppm (fresh prunes)<br>4 ppm (dried prunes)<br>No preharvest interval through 1.5 pounds per acre for foliar application.<br>Do not apply more than 3 pounds per acre during the growing season.<br>Do not feed or allow livestock to graze on cover crops growing in treated areas. |

Refer to Nectarine cluster.

CYHEXATIN

| | Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations |
|---|---|---|---|
| 01016AA | Strawberry | | 3 ppm<br>1 day preharvest interval through 1.25 pound per acre for foliar application. |
| LAVBEA | Twospotted spider mite | 0.375-0.5 lb/ 100 gal [150-250 gal/A] (50% WP) | Foliar application. Apply a minimum of 0.75 pound per acre per application. Apply higher rates in planting with dense foliage or to prolong the interval between applications. In CA and FL, it will sometimes be desirable to apply at 7 to 14 day intervals during periods of intense mite pressure. |
| | TERRESTIAL NON-FOOD CROP | | |
| | (Ornamentals) | | |
| 32000AA<br>31057CA<br>3[illegible]A<br>3[illegible]A<br>3[illegible]A | Ornamental Plants | | Apply to the foliage only of chrysanthemums (prebloom) and poinsettias (prebract) to avoid possible injury to blossoms and bracts. |
| LAVBEA | Twospotted spider mite | 0.125-0.1875 lb/100 gal (50% WP) | Foliar application. |
| | GREENHOUSE NON-FOOD CROP | | |
| | (Ornamentals) | | |
| 31057CA | Carnation | | Refer to TERRESTIAL NON-FOOD CROP, (Ornamentals) Ornamental Plants. |
| 31065CA | Chrysanthemum | | |
| 31159CA | Poinsettia | | |
| 34120CA | Rose | | |

CYHEXATIN

| Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations |
|---|---|---|
| AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS | | |
| )01500 AAAAAA Aerial Application | | |
| — | | Refer to TERRESTRIAL FOOD CROP Apple, Citrus Fruits, Pear. |

CYHEXATIN

Listing of Registered Pesticide Products by Formulation

01 95% technical chemical
cyhexatin (101601)
000464-00451

50.0006 50% wettable powder
cyhexatin (101601)
000239-02414 000464-00393

999999 State Label Registrations

CA Reg. No.
000239-05851 000464-06840 010965-09999 010965-10000
035296-05819

WA Reg. No.
000464-06841

Listing of Registration Numbers by Site/Pest and Formulation

TERRESTRIAL FOOD CROP

03001AA Almond
LAVASA European red mite
LAVBAA Pacific spider mite
LAVBEA Twospotted spider mite
(50% WP)
000239-02414 000464-00393

04001AA Apple
LAJAKA Apple rust mite .
LAVASA European red mite
LAVAYA McDaniel spider mite
LAVBAA Pacific spider mite
LAVBBA Schoene spider mite
LAVBEA Twospotted spider mite
LAVAEA Yellow spider mite
(50% WP)
000239-02414 000464-00393

02000AA Citrus Fruits (including grapefruit, lemon, lime, orange, and tangerine)
LAVCA Citrus red mite
LAJCA Citrus rust mite
LAVBA Pacific spider mite
LAVTA Texas citrus mite
(50% WP)
000239-02414 000464-00393

08020AA Hops
LAVBEA Twospotted spider mite
(50% WP)
000239-02414 000464-00393

05003AA Nectarine
LAVASA European red mite
LAVAYA McDaniel spider mite
LAVBAA Pacific spider mite
LAJAIA Peach silver mite
LAVBEA Twospotted spider mite
(50% WP)
000239-02414 000464-00393

Listing of Registration Numbers by Site/Pest and Formulation (continued)

)5004AA Peach
LAVASA European red mite
LAVAYA McDaniel spider mite
LAVBAA Pacific spider mite
LAJAIA Peach silver mite
LAVBEA Twospotted spider mite
(50% WP)
000239-02414 000464-00393

)4003AA Pear
LAJAKA Apple rust mite
LAVASA European red mite
LAVAYA McDaniel spider mite
LAVBAA Pacific spider mite
LAJAOA Pear rust mite
LAVBBA Schoene spider mite
LAVBEA Twospotted spider mite
LAVAEA Yellow spider mite
(50% WP)
000239-02414 000464-00393

050[illegible] Plum (Prune)
LA[illegible] European red mite
L[illegible] McDaniel spider mite
L[illegible] Pacific spider mite
LAJAIA Peach silver mite
LAVBEA Twospotted spider mite
(50% WP)
000239-02414 000464-00393

01016AA Strawberry
LAVBEA Twospotted spider mite
(50% WP)
000239-02414 000464-00393

)3009AA Walnuts
LAVASA European red mite
LAVBAA Pacific spider mite
LAVBEA Twospotted spider mite
(50% WP)
000239-02414 000464-00393

Listing of Registration Numbers by Site/Pest and Formulation (continued)

TERRESTRIAL NON-FOOD CROP

(Ornamentals)

32000AA
LAVBEA — Ornamental Plants
Twospotted spider mite
(50% WP)
000239-02414 000464-00393

GREENHOUSE NON-FOOD CROP

(Ornamentals)

31057CA
LAVBEA — Carnation
Twospotted spider mite
(50% WP)
000239-02414 000464-00393

31065CA
LAVBEA — Chrysanthemum
Twospotted spider mite
(50% WP)
000239-02414 000464-00393

[illegible]9CA
LAVBEA — Poinsettia
Twospotted spider mite
(50% WP)
000239-02414 000464-00393

34120CA
LAVBEA — Rose
Twospotted spider mite
(50% WP)
000239-02414

## REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1/] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2/] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

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(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

## III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B--Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

## IV. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

## A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

| Size of Label on Front Panel in Square Inches | Signal Word Minimum Type Size All Capitals | "Keep Out of Reach of Children" Minimum Type Size |
|---|---|---|
| 5 and under | 6 point | 6 point |
| above 5 to 10 | 10 point | 6 point |
| above 10 to 15 | 12 point | 8 point |
| above 15 to 30 | 14 point | 10 point |
| over 30 | 18 point | 12 point |

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

A. Classification Labeling Requirements

If Section I of this Guidance Document indicates that your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

B. Compliance Schedules

No product with a use classified for restricted use under this Standard may be released for shipment by the registrant or producer after one year from the date of issuance of this Standard, unless such product bears the restricted use classification. All products still in channels of trade after two years from the date of issuance of this Standard must be labeled for restricted use.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing (name of pesticide) as an active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to tne Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data.

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 (enclosed) for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing (name of pesticide) in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing (name of pesticide) alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data. (Refer to Table C).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 (enclosed) for latest requirements.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing (name of pesticide) either as the sole active ingredient or in combination with other active ingredients

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Applications and other required information should be submitted to the following address:

Product Manager
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703)

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

Appendix II-1

## Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Cyhexatin Standard

MRID CITATION


00018842 Atkins, E.L., Jr.; Anderson, L.D.; Greywood, E.A. (1969) Effect of Pesticides on Apiculture: Project No. 1499; Research Report CF-7501. (Unpublished study received May 8, 1971 under 1F1174; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Ciba Agrochemical Co., Summit, N.J.; CDL:090973-B)

00034893 Smith, G.N.; Fischer, F.S.; Axelson, R.J. (1970) The Volatilization and Photodecomposition of Plictran (R) Miticide. (Unpublished study received Jul 20, 1970 under 0F1005; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:091734-B)

00034894 Smith, G.N.; Axelson, R.J.; Schiesser, L.H. (1970) The Loss of Plictran (R) Miticide from Various Soils. (Unpublished study received Jul 20, 1970 under 0F1005; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:091734-D)

00034895 Whitney, W.K.; Hummel, R.A.; Bartel, J. (1966) Leaching Tests with Dowco 213 in Soil. (Unpublished study received Jul 20, 1970 under 0F1005; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:091734-E)

00040803 Getzendaner, M.E.; Corbin, H.B.; Stewart, D.; et al. (1973) Residues of Tricyclohexyltin hydroxide on Apples and Pears|. Includes method ACR 73.2 dated May 1, 1973. (Unpublished study received May 23, 1973 under 3F1400; prepared in cooperation with M & T Chemicals, Inc. and others, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:091962-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Cyhexatin Standard

MRID CITATION

00052033 Komblas, K.N. (1969) Determination of Residues of Plictran Acaricide on Apples and Pears in Italy. (Translation; unpublished study received Mar 10, 1969 under 9G0815; prepared by Societa Italo-Americana Produtti Antipararassitari, Italy, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:093133-J)

00065984 Dow Chemical U.S.A. (1969) Summary and Conclusions: Plictran. (Unpublished study received Jul 20, 1970 under 0F1005; CDL: 091735-A)

00065985 Getzendaner, M.E. (1968) A Review of Residue Information on Tricyclohexyltin Hydroxide. Includes method dated Jul 18, 1967; method no. V-Or-47 dated May 2, 1966; method no. V-Or-48 dated May 2, 1966; method no. V-Or-51 dated Aug 15, 1966. (Unpublished study received Jul 20, 1970 under 0F1005; CDL:091735-B)

00065986 Getzendaner, M.E.; Corbin, H.B. (1969) Inorganic and Organic Tin Compounds in or on Apples and Pears from Field Applications of Plictran (R) Miticide. (Unpublished study received Jul 20, 1970 under 0F1005; prepared in cooperation with M & T Chemicals, Inc., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 091735-D)

00065987 Getzendaner, M.E.; Corbin, H.B. (1969) Inorganic and Organic Tin Residues in or on Apples and Pears from Field Applications of Plictron (R) Miticide. (Unpublished study received Jul 20, 1970 under 0F1005; prepared in cooperation with M & T Chemicals, Inc., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 091735-E)

00065991 Corbin, H.B. (1970) Separation and determination of trace amounts of tin present as organotin residues on fruits. Journal of the Association of Official Analytical Chemists 53(1):140-146. (Also in unpublished submission received Jul 20, 1970 under 0F1005; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:091735-I)

00065993 M & T Chemicals, Incorporated (19??) Recovery of Total Tin from Apple with Arsenic Present: TA-6-1 with Arsenic Elimination Modification. (Unpublished study received Jul 20, 1970 under 0F1005; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 091735-K)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Cyhexatin Standard


MRID CITATION

00071437 Norton, E.J. (1980) Organotin Residues in Pecan Nutmeats and Shells after Treatment with Plictran 50W Miticide. (Unpublished study received Mar 19, 1981 under 464-393; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099953-A)

00080462 Smith, G.N.; Axelson, R.J. (1969) Radiotracer Evaluation of the Uptake of Tricyclohexyltin Hydroxide from Various Soils by Bean, Radish, and Corn Plants. (Unpublished study received Jun 5, 1969 under 9F0815; submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:091406-L)

00080464 Wazeter, F.X.; Buller, R.H.; Geil, R.G.; et al. (1968) Acute Oral Toxicity Study in the Wistar Rat: 221-031. (Unpublished study received Jun 5, 1969 under 9G0815; prepared by International Research and Development Corp., submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:091406-N)

00080472 Starnes, C.J. (1966) Stability of Tricyclohexylhydroxy Tin to Sunlamp Exposure: AL No. S-66-648. (Unpublished study received Jun 5, 1969 under 9G0815; submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:091406-X)

00081485 Smith, G.N.; Fischer, F.S.; Axelson, R.J. (1968) The Volatilization and Photodecomposition of Plictran (R) Miticide. (Unpublished study received Jun 5, 1969 under 9G0815; submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:091406-AH)

00081487 Whitney, W.K.; Kenaga, E.E. (1966) Bioassay Experiments To Determine the Volatility of Tricyclohexyltin Hydroxide. (Unpublished study received Jun 5, 1969 under 9G0815; submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:091406-AJ)

00081491 Smith, G.N. (1969) A Simple Method for Combusting Tissues for Tin--Sn 119 Analysis. (Unpublished study received Jun 5, 1969 under 9G0815; submitted by Dow Chemical Co., Indianapolis, Ind.; CDL: 091406-AN)

00081739 Batchelder, T.L. (1967) Acute Fish Toxicity of Tricyclohexyltin Hydroxide to Three Species of Fish. (Unpublished study received Jun 6, 1969 under 9G0815; submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:091407-F)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Cyhexatin Standard

MRID CITATION

00081743 Duddles, G.A. (1968) The Acute Fish Toxicity of Cyclohexyl Stannoic Acid. (Unpublished study received Jun 6, 1969 under 9G0815; submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:091407-K)

00081748 Laker, T.L.; Elsea, J.R.; Ede, M. (1966) Repeated Insult Patch Test on M-2527 and Cloth Material TE98-S.E.U.3501: Report Q-246. (Unpublished study, including letter dated Sep 26, 1966 from K.J. Olson to G.E. Lynn, received Jun 6, 1969 under 9G0815; prepared by Hill Top Research, Inc., submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:091407-P)

00108766 Interregional Research Project No. 4 (1973) Plictran: Residues in Hops. (Compilation; unpublished study received Jun 7, 1973 under 3E1405; CDL:093758-B)

00112178 Shellenberger, T. (1971) Acute Toxicological Evaluations of Dowco 213 and Plictran 50W Miticide with Bobwhite and Japanese Quail: GSRI Project No. NC-471. Final rept. (Unpublished study received Dec 6, 1971 under 464-393; prepared by Gulf South Research Institute, submitted by Dow Chemical U.S.A., Midland, MI; CDL:003643-B)

00112180 Leong, B.; Jersey, G. (1972) Acute Inhalation Toxicity of Plictran 50W Miticide. (Unpublished study received Feb 14, 1973 under 464-470; submitted by Dow Chemical U.S.A., Midland, MI; CDL: 003678-B)

00112181 Getzendaner, M. (1973) A Study of Residues of Tin in Apples and Pears from Applications of Plictran Miticide as a 2% Dust by Helicopter: GHC 625. (Unpublished study received Feb 14, 1973 under 464-470; submitted by Dow Chemical U.S.A., Midland, MI; CDL:003678-C)

00112183 Rampy, L.; Keeler, P. (1973) Acute Eye Irritation Studies Conducted on Trichyclohexyltin Hydroxide. (Unpublished study received Nov 6, 1973 under 464-393; submitted by Dow Chemical U.S.A., Midland, MI; CDL:050104-A)

00112187 Dow Chemical Co. (1969) Full Reports of Investigations Made with Respect to the Safety of the Pesticide Chemical: Tricyclohexyltin Hydroxide. Summary of studies 091408-B through 091408-N, 091737-A through 091737-C, 091406-K, 091737-E, and 091406-L through 091406-N. (Compilation; unpublished study received Jun 6, 1969 under 9G0815; CDL:091408-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Cyhexatin Standard

MRID CITATION

00112206 Dow Chemical Co. (1970) Tin Content of Tissues of Rats and Dogs Fed Varying Amounts of Tricyclohexyltin Hydroxide in the Daily Diet for Two Years. (Unpublished study received Jul 20, 1970 under OF1005; CDL:091737-B)

00112207 Dow Chemical Co. (1970) Study of Tin Residues in Dairy Products and Tissue from Cattle Fed Tricyclohexyltin Hydroxide. (Compilation; unpublished study received Jul 20, 1970 under OF1005; CDL:091737-C)

00112208 Smith, G.; Taylor, Y. (1970) The Absorption and Translocation of Plictran Miticide and Its Decomposition Products in Bean and Corn Plants. (Unpublished study received Jul 20, 1970 under OF1005; submitted by Dow Chemical Co., Indianapolis, IN; CDL: 091737-E)

00112215 Wazeter, P.; Buller, R.; Geil, R.; et al. (1969) 21 Day Dermal Study in Albino Rabbits: Plictran M-3180: 221-064. (Unpublished study received Jul 20, 1970 under OF1005; prepared by International Research and Development Corp., submitted by Dow Chemical Corp., Indianapolis, IN: CDL:091738-J)

00112217 Dow Chemical Co. (1970) Full Reports of Investigtions Made with Respect to the Safety of the Pesticide Chemical: Tricyclohexyltin Hydroxide. Summary of studies 091407-L, 091408-B through 091408-N and 091738-B through 091738-J. (Unpublished study received Jul 20, 1970 under OF1005; CDL:091743-A)

00112218 Dow Chemical Co. (1972) Study: Tricyclohexyltin Hydroxide Residue in Meat, Fat, and Meat Byproducts--Dairy Cattle. (Compilation; unpublished study received on unknown date under OF1005; CDL: 091744-A)

00112220 Dow Chemical Co. (1972) Study: Tricyclohexyltin Hydroxide Residue in Meat & Milk. (Compilation; unpublished study received on unknown date under OF1005; CDL:093315-A)

00112225 Interregional Research Project No. 4 (1975) The Results of Tests on the Amount of Tricyclohexyltin Hydroxide Residue Remaining in or on Macadamia Nuts, Including a Description of the Analytical Methods Used. (Compilation; unpublished study received Nov 20, 1975 under 6E1706; CDL:097367-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Cyhexatin Standard

MRID CITATION

00112230 Dow Chemical U.S.A. (1975) Residues: Tricyclohexyltin Hydroxide in or on Crop and Animal Products. (Compilation; unpublished study received Jun 11, 1975 under 5F1641; CDL:097475-C)

00112232 Dow Chemical U.S.A. (1976) Study: Plictran 50W Residue on Grapes and Raisins. (Compilation; unpublished study received Feb 17, 1976 under 5F1641; CDL:097508-A)

00112236 Dow Chemical U.S.A. (1975) Performance and Residue Data: Aerial Application of Plictran 50W Miticide on Apples, Pears, Citrus. (Compilation; unpublished study received Apr 10, 1975 under 464-393; CDL:220007-A)

00112237 Dow Chemical U.S.A. (1975) Residue Data in Support of Concentrated Applications of Plictran 50W Miticide on Stone Fruits and Nuts. (Compilation; unpublished study received Apr 28, 1975 under 464-393; CDL:220413-A)

00138963 Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemcals to Fish and Aquatic Invertebrates. By U.S. Fish and Wildlife Service. Washington, D.C.: USFWS. (Resource publication 137; also in unpublished submission received Feb 6, 1984 under 239-2424; submitted by Chevron Chemical Co., Richmond, CA; CDL: 252355-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Cyhexatin Standard


GS-00237001 Dow Chemical Co. 1971. Determination of small amounts of organotin in macertaed fruit. Method No. TA-2-3. [Submitted under PP#3F1312 (117973).]

GS-00237002 Dow Chemical Co. 1971. Determination of small amounts of tin in fruit. Method No. TA-6-2. [Submitted under PP#3F1312 (117973).]

GS-00237003 Dow Chemical Co. 1971. Determination of total and organic tin on orange oil. Method No. TA-19. [Submitted under PP#3F1312 (117973).]

GS-00237004 Dow Chemical Co. 1972. Trace organotin in the presence of inorganic tin. Method No. TA-29. [Submitted under PP#3F1312 (117973).]

GS-00237005 Dow Chemical Co. 1972. Gas chromatographic method for the determination of tricyclohexyltin hydroxice in organge juice. Method No. ACR 72.11. [Submitted under PP#3F1312 (117973)].

GS-00237006 Kovacs, M. 1972. Method trail on GLC confirmatory method for Plictran in liver; in correspondence file of PP#3F1005.

GS-00237007 Makhijani, G. 1971. Report on method tryout for Plictran; in correspondence file of 0F1005.

GS-00237008 Makhijani, G. 1973. Report on method trial for Plictran in meat and milk; in correspondence file of PP#0F1005.

GS-00237009 Seibert, E. 1971. Method tryout for Plictran on apples; in correspondence file of PP#0F1005.

OMB Approval No. 2070-0056

## FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

| REGISTRANT'S AUTHORIZED REPRESENTATIVE | SIGNATURE | DATE |
|---|---|---|
| | | |

EPA Form 8580-1 (10-82)

| Registration Guideline No. | Name of Test | Test not required for my product listed above (check below) | I am complying with data requirements by | | (For EPA Use Only) Accession Numbers Assigned |
|---|---|---|---|---|---|
| | | | Citing MRID# | Submitting Data (Attached) | |
| 63-13 | Stability | | | | |
| 63-14 | Oxidizing/reducing reaction | | | | |
| 63-15 | Flammability | | | | |
| 63-16 | Explodability | | | | |
| 63-17 | Storage stability | | | | |
| 63-18 | Viscosity | | | | |
| 63-19 | Miscibility | | | | |
| 63-20 | Corrosion characteristics | | | | |
| 63-21 | Dielectric breakdown voltage | | | | |
| §158.135 TOXICOLOGY | | | | | |
| 81-1 | Acute oral LD-50, rat | | | | |
| 81-2 | Acute dermal LD-50 | | | | |
| 81-3 | Acute inhalation, LC-50 rat | | | | |
| 81-4 | Primary eye irritation, rabbit | | | | |
| 81-5 | Primary dermal irritation | | | | |
| 81-6 | Dermal sensitization | | | | |

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

| Registration Guideline No. | Name of Test | Test not required for my product listed above (check below) | I am complying with data requirements by | | (For EPA Use Only) Accession Numbers Assigned |
|---|---|---|---|---|---|
| | | | Citing MRID# | Submitting Data (Attached) | |
| §158.20 PRODUCT CHEMISTRY | | | | | |
| 61-1 | Identity of ingredients | | | | |
| 61-2 | Statement of composition | | | | |
| 61-3 | Discussion of formation of ingredients | | | | |
| 62-1 | Preliminary analysis | | | | |
| 62-2 | Certification of limits | | | | |
| 62-3 | Analytical methods for enforcement limits | | | | |
| 63-2 | Color | | | | |
| 63-3 | Physical state | | | | |
| 63-4 | Odor | | | | |
| 63-5 | Melting point | | | | |
| 63-6 | Boiling point | | | | |
| 63-7 | Density, bulk-density, or specific gravity | | | | |
| 63-8 | Solubility | | | | |
| 63-9 | Vapor pressure | | | | |
| 63-10 | Dissociation constant | | | | |
| 63-11 | Octanol/water partition coefficient | | | | |
| 63-12 | pH | | | | |

grant obtained the data from another firm (identify), applicant copied data from a publication, applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii)) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.8–5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on) the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27963, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 3(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.18, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.8(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after (date)."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any



inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

| Hazard indicators | Toxicity categories | | | |
|---|---|---|---|---|
| | I | II | III | IV |
| Oral $LD_{50}$ | Up to and including 50 mg/kg | From 50 thru 500 mg/kg | From 500 thru 5000 mg/kg | Greater than 5000 mg/kg |
| Inhalation $LC_{50}$ | Up to and including 2 mg/liter | From 2 thru 2 mg/liter | From 2 thru 20 mg/liter | Greater than 20 mg/liter |
| Dermal $LD_{50}$ | Up to and including 200 mg/kg | From 200 thru 2000 | From 2,000 thru 20,000 | Greater than 20,000 |
| Eye effects | Corrosive; corneal opacity not reversible within 7 days | Corneal opacity reversible within 7 days; irritation persisting for 7 days | No corneal opacity; irritation reversible within 7 days | No irritation |
| Skin effects | Corrosive | Severe irritation at 72 hours. | Moderate irritation at 72 hours | Mild or slight irritation at 72 hours |

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "Keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, [illegible] permit reasonable variations [illegible] placement of the statement of [illegible]

cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

| Size of label front panel in square inches | Points | |
|---|---|---|
| | Required signal word, all capitals | "Keep out of reach of Children" |
| 5 and under | 6 | 6 |
| Above 5 to 10 | 10 | 6 |
| Above 10 to 15 | 12 | 8 |
| Above 15 to 30 | 14 | 10 |
| Over 30 | 18 | 12 |

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

| Toxicity category | Precautionary statements by toxicity category | |
|---|---|---|
| | Oral, inhalation, or dermal toxicity | Skin and eye local effects |
| I | Fatal if swallowed. If swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.] | Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.] |
| II | May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.] | Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.] |
| III | Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.] | Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists. |
| IV | [No precautionary statements required.] | [No precautionary statements required.] |

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral $LD_{50}$ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute $LC_{50}$ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral $LD_{50}$ of 100 mg/kg or less, or a subacute dietary $LC_{50}$ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

| Flash point | Required text |
|---|---|
| (A) Pressurized Containers | |
| Flash point at or below 20° F; if there is a flashback at any valve opening | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame | Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| All other pressurized containers | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| (B) Nonpressurized Containers | |
| At or below 20° F | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| Above 20° F and not over 80° F | Flammable. Keep away from heat and open flame. |
| Above 80° F and not over 150° F | Do not use or store near heat or open flame. |

(i) *Directions for use.*—(1) *General requirements.*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use.*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing pr
provided that:



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(continued)

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28288, July 3, 1975; 40 FR 32339, Aug. 1, 1975; 40 FR 36971, Aug. 21, 1975, as amended at 43 FR 5780, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing—*(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional

RESTRICTED USE PESTICIDE
PRODUCT NAME
KEEP OUT OF REACH OF CHILDREN
DANGER—POISON
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS (& DOMESTIC ANIMALS)
DANGER
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
RE-ENTRY STATEMENT
(If Applicable)
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
CROP
WARRANTY STATEMENT
ACTIVE INGREDIENT
INERT INGREDIENTS
TOTAL
100.00 %
THIS PRODUCT CONTAINS
LBS OF
PER GALLON
NET CONTENTS

## LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 1 | Product name | All products | Front panel | Center front panel | |
| 2 | Company name and address | All products | None | Bottom front panel or end of label text | If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc. |
| 3 | Net contents | All products | None | Bottom front panel or end of label text | May be in metric units in addition to U.S. units |
| 4 | EPA Reg. No. | All products | None | Front panel | Must be in similar type size and run parallel to other type. |
| 5 | EPA Est. No. | All products | None | Front panel, immediately before or following Reg. No. | May appear on the container instead of the label. |
| 6A | Ingredients statement | All products | Front panel | Immediately following product name | Text must run parallel with other text on the panel. |
| 6B | Pounds/gallon statement | Liquid products where dosage given as lbs. ai/unit area | Front panel | Directly below the main ingredients statement | |
| 7 | Front panel precautionary statements | All products | Front panel | | All front panel precautionary statements must be grouped together, preferably blocked. |
| 7A | Keep Out of Reach of Children (Child hazard warning) | All products | Front panel | Above signal word | Note type size requirements. |
| 7B | Signal word | All products | Front panel | Immediately below child hazard warning | Note type size requirements. |

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 7C | Skull & crossbones and word POISON (in red) | All products which are Category I based on oral, dermal, or inhalation toxicity | Front panel | Both in close proximity to signal word | |
| 7D | Statement of practical treatment | All products in Categories I, II, and III | Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements. | Front panel for all. | |
| 7E | Referral statement | All products where precautionary labeling appears on other than front panel. | Front panel | | |
| 8 | Side/back panel precautionary statements | All products | None | Top or side of back panel preceding directions for use | Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked. |
| 8A | Hazards to humans and domestic animals | All products in Categories I, II, and III | None | Same as above | Must be preceded by appropriate signal word. |
| 8B | Environmental hazards | All products | None | Same as above | Environmental hazards include bee caution where applicable. |

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 8C | Physical or chemical hazards | All pressurized products, others with flash points under 150°F | None | Same as above | |
| 9A | Restricted block | All restricted products | Top center of front panel | Preferably blocked | Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word. |
| 9C | Misuse statement | All products | Immediately following heading of directions for use | | |
| 10A | Reentry statement | All cholinesterase inhibitors | In the directions for use | Immediately after misuse statement | |
| 10C | Storage and disposal block | All products | In the directions for use | Immediately before specific directions for use or at the end of directions for use | Must be set apart and clearly distinguishable from from other directions for use. |
| 10D | Directions for use | All products | None | None | May be in metric as well as U.S. units |

## PHYSICAL-CHEMICAL HAZARDS

| Criteria | Required Label Statement |
|---|---|
| I. Pressurized Containers | |
| A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening. | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening. | Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| C. ALL OTHER PRESSURIZED CONTAINERS | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| II. Non-Pressurized Containers | |
| A. Flashpoint at or below 20°F. | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| B. Flashpoint above 20°F and not over 80°F. | Flammable. Keep away from heat and open flame. |
| C. Flashpoint over 80°F and not over 150°F. | Do not use or store near heat and open flame. |
| D. Flashpoint above 150°F. | None required. |

## STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

| Size of label front panel in square inches | Required type size for the heading STORAGE AND DISPOSAL (all capitals) |
|---|---|
| 10 and under | .6 point |
| Above 10 to 15 | .8 point |
| Above 15 to 30 | 10 point |
| Over 30 | 12 point |

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

| Container Type | Statement |
|---|---|
| Non-aerosol products (bottles, cans, jars) | Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash. |
| Non-aerosol products (bags) | Do not reuse bag. Discard bag in trash. |
| Aerosol products | Replace cap and discard containers in trash. Do not incinerate or puncture. |

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

| Container Type | Statement |
|---|---|
| Metal containers (non-aerosol) | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. |
| Plastic containers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. |
| Glass containers | Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures. |
| Fiber drums with liners | Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused1, dispose of in the same manner. |
| Paper and plastic bags | Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. |
| Compressed gas cylinders | Return empty cylinder for reuse (or similar wording) |

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®
Vinyl chloride
Xylene